MAR 8 - 2005

K050111

510(k) Summary

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Edward E. Newton
Director, Regulatory Affairs
Phone: (512) 435-3407
Fax: (512) 435-3350

DATE PREPARED: January 10, 2005

DEVICE TRADE NAME: SMARxT® BMR1900™Closed Venous Reservoir Bag

COMMON/USUAL NAME: Venous Reservoir Bag

CLASSIFICATION NAME: Cardiopulmonary Bypass Blood Reservoir

PREDICATE DEVICE: SMARxT® VRB® 1800™ Closed Venous Reservoir Bag

DEVICE DESCRIPTION AND INDICATIONS FOR USE:

The SMARxT BMR1900 Closed Venous Reservoir Bag is a sterile device with a non-pyrogenic fluid pathway, for single use only, and is not intended to be resterilized by the user. The device is a soft-shelled blood reservoir designed for use in cardiopulmonary bypass surgery for periods up to six hours. The SMARxT BMR1900 can be operated at flow rates up to 6 liters per minute. The maximum operating volume is 1900 mL. The minimum operating volume is 300 mL.

The SMARxT BMR1900 has a blood inlet port with an integral cardiotomy inlet on one side of the bag and a blood outlet port on the opposite side of the bag. Integral to the blood inlet port are connectors for measuring the temperature and saturation/hematocrit of the incoming blood using external monitoring equipment. The top edge of the bag has a dual four-way stopcock assembly that is used to purge air from the bag. The stopcock assembly may also be used for the administration of drugs or other solutions, as needed during the cardiopulmonary bypass procedure. Blood enters the bag through the inlet port and passes through a polyester screen filter before exiting the bag through the outlet port. The purpose of the filter is to facilitate the removal of large air bubbles from the blood.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

A comparison of device features and in-vitro test data demonstrate that the COBE SMARxT BMR1900 Closed Venous Reservoir Bag is substantially equivalent to the currently marketed COBE SMARxT VRB1800 Closed Venous Reservoir Bag (K980786).

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information contained in this submission is attached as Appendix O.

Further Information

In the event that additional information is required, please contact:

Edward E. Newton
Director, Regulatory Affairs
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(COBE Cardiovascular, Inc. and Carbomedics, Inc.)
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 - 2005

Cobe Cardiovascular, Inc.
c/o Mr. Edward E. Newton
Director, Regulatory Affairs
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K050111
SMARxT BMR 1900 Closed Venous Reservoir Bag
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: January 17, 2005
Received: January 18, 2005

Dear Mr. Newton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K050111

Device Name: SMARxT® BMR1900™ Closed Venous Reservoir Bag

Indications For Use:

The SMARxT® BMR1900™ Closed Venous Reservoir Bag is intended to be used in cardiac surgical procedures requiring extracorporeal support for periods of up to six hours.

Prescription Use __X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vidmar

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050111